

From: [Bill Jacobs](#)  
To: [Jonathan D Berger](#)  
Bcc: [Dan Peacock](#); [Kimberly Nesci](#); [Jennifer Gaines](#)  
Subject: Re: efficacy and other data required to register a new rodenticide  
Date: 02/17/2011 10:26 AM

If the active ingredient is not currently registered, we would regard it as a new chemical, with basic chemistry, product chemistry, acute toxicity, ecological toxicity data being required, plus any additional studies triggered by the results of the basic studies, the nature of the proposed use sites, or other considerations.

If you intend to produce a new bait using a registered source for uses that the manufacturing-use product specifically authorizes, the requirements for new data could be limited to product chemistry and laboratory efficacy data for the specific new formulation. There might be some additional requirements depending upon specific circumstances (e.g., the active ingredient selected, whether equivalence between wild-type and laboratory strains of target species had been established for the in laboratory efficacy trials for the target species for that active ingredient, etc.).

If the active ingredient currently is registered but you wish to register a new source for it, you would have to document the composition of the new source product via assays and other chemistry data. EPA would then have to find the new source to be sufficiently similar to a registered source in order for other data on the registered source to be applicable to the new source. How much you might have to provide in terms of additional new data would be affected by the results of the similarity assessment plus the nature of the use patterns sought.

The PRIA application fees would vary considerably according to which route toward registration that you chose to use.

The protocols for laboratory efficacy trials needed to support claims for controlling commensal rats and house mice with an acute dry bait formulation are 1.209 and 1.210. I can supply these protocols to you if you do not have them.

In our telephone conversation earlier today, you mentioned possibly wanting to meet with IRB on this matter during the week of March 13. Let us know possible dates and times that you would propose for such a meeting.

▼ [Re: efficacy and other data required to register a new rodenticide](#)

Re: efficacy and other data required to register a new rodenticide

Jonathan D Berger to: Bill Jacobs

02/17/2011  
09:25 AM

Bill, thanks for the response. It is a "greener" item which I believe was registered before but we have redone how the active is presented. It is more than just taking an already registered active and putting it in a bait. But if its not too difficult let me know both. Thanks

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Are you interested in registering a new rodenticide active ingredient ("new chemical") or a new product containing an active ingredient that already is registered (i.e., an "old chemical")? It makes a huge difference.

efficacy and other data required to register a new rodenticide

Jonathan D Berger to:  
Bill Jacobs

02/16/2011 08:46 PM

Bill, long time since we have talked. BASF is thinking about registering a new rodenticide. I have been looking through EPA websites

and cannot get a handle on what efficacy and safety data is required. I need to put together a budget in the next couple of days. Can you point me to the right web site that lists the studies and might we talk on the phone sometime tomorrow about this. Thanks in advance for your help.

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